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Patentanmeldung Nr. Patent application No. Demande de brevet n°

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Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
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Si aucun titre n'est indiqué se referer à la description.)

Prostehic device for cartilage repair

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Prosthetic Device for Cartilage Repair

The present invention is directed to a triphasic prosthetic device for repairing or replacing cartilage or cartilage-like tissues. Said prosthetic devices are useful as articular cartilage substitution material and as scaffold for regeneration of articular cartilagenous tissues.

Articular cartilage tissue covers the ends of all bones that form diarthrodial joints. The resilient tissues provide the important characteristic of friction, lubrication, and wear in a joint. Furthermore, it acts as a shock absorber, distributing the load to the bones below. Without articular cartilage, stress and friction would occur to the extent that the joint would not permit motion. Articular cartilage has only a very limited capacity of regeneration. If this tissue is damaged or lost by traumatic events, or by chronic and progressive degeneration, it usually leads to painful arthrosis and decreased range of joint motion.

Recently, the structure of rabbit articular cartilage has been further elucidated in an article by I. ap Gwynn et al, European Cells and Materials, Vo. 4, pp. 18-29, 2002. The tibial articular cartilage has been shown to comprise a radial zone in which the aggrecan component of the extracellular matrix was arranged generally oriented in columns in the radial direction. As a terminating member a superficial zone, next to the tibial plateau, is provided and having a spongy collagen architecture.

Several methods have been established in the last decades for the treatment of injured and degenerated articular cartilage. Osteochondroal transplatation, microfracturing, heat treatment for sealing the surface, shaving, autologous chondrocyte transplantation (ACT), or total joint replacement are among the common techniques applied in today's orthopedic surgery.

Joint replacement techniques where metal, ceramic and/or plastic components are used to substitute partially or totally the damaged or degenerated joint have already a long and quite successful tradition. The use of allograft material has been successful to some extent for small transplants, however, good quality allografts are hardly available.

Osteochondroal transplantation (i.e. mosaicplasty) or autologous chondrocyte transplantation (ACT) are applied whenever total joint replacement is not yet indicated. These methods can be used to treat small and partial defects in a joint. In mosaicplasty defects are filled with osteochondral plugs harvested in non-load bearing areas. In ACT, chondrocytes are harvested by biopsy and grown in-vitro before a highly concentrated cell suspension is injected below an membrane (artificial or autologous) covering the defect area.

Commonly, the replacement of cartilage tissue with solid permanent artificial inserts has been unsatisfactorily because the opposing articular joint surface is damaged by unevenness or by the hardness of the inserts. Therefore, the transplantation technology had to take a step forward in the research of alternative cartilage materials such as biocompatible materials and structures for articular cartilage replacement.

For example, U.S. Pat. No. 5,624,463 describes a prosthetic articular cartilage device comprising a dry, porous volume matrix of biocompatible and at least bioresorbable fibres and a base component. Said matrix establishes a bioresorbable scaffold adapted for the ingrowth of articular chondrocytes and for supporting natural articulating joint forces. Useful fibres include collagen, reticulin, elastin, cellulose, alginic acid,

chitosan or synthetic and biosynthetic analogs thereof. Fibres are ordered in substantially circumferentially extending or substantially radially extending orientations. The base component is provided as a support on which the fiber matrix is applied. It is configured to fit in a complementary aperture in defective bone to secure the position of such a device in the bone. The base component is a composite material comprising a dispersion of collagen and composition consisting of tricalcium phosphate and hydroxyapatite.

It has been shown, however, that the function of the above construction has not been always satisfactory. The reason is that said known prosthetic articular cartilage device is frequently unstable due to its structure and thus had to be replaced in the joint area by another surgical operation in to again repair cartilage joints such as knee and hip.

In view of this situation, in the field of articular cartilage replacement materials, there is a need for a structure suitable as a prosthetic articular cartilage which is made of natural resorbable materials or analogs thereof and having an improved structure stability and an accurate positioning in the bone. At the same time, the prosthetic device should be biomechanically able to withstand normal joint forces and to promote repair and replacement of cartilage tissue or cartilage-like tissue.

These objects are solved by the prosthetic device according to claim 1.

The present invention relates to a prosthetic device for repairing or replacing cartilage or cartilage-like tissue which comprises a polymeric hollow body component 3, with a number of oriented hollow bodies, a base component 4 to anchor said polymeric hollow body component 3 in or onto an osteochondral environment and at least one superficial layer comprising randomly oriented fibres 2 provided on said polymeric hollow body component 3, wherein said number of highly oriented hollow bodies of the polymeric hollow body component 3 are aligned essentially in parallel to the insertion axis of the prosthetic device, i.e. perpendicularly to the plane of the articulating surface.

The subclaims concern preferred embodiments of the prosthetic device of the present invention.

It has been surprisingly found that the stability of a prosthetic articular cartilage device can be essentially improved by providing a polymeric hollow body component with a number of highly oriented hollow bodies 3 in such a way that the hollow bodies are aligned essentially in parallel to the insertion axis of the prosthetic device. The polymeric hollow body component is flanked by a base

component and a superficial layer to form the triphasic structure of the device of the invention. The specific alignment of the hollow bodies in the layer perfectly mimics the cartilage and cartilage-like tissues providing an excellent mechanical stability. At the same time, a basis for rapid cartilage in-growth is provided, thus assuring a long term cartilage replacement.

The invention itself may be more fully understood from the following description when read together with the accompanying Figures wherein

Fig. 1 shows a vertical cross-sectional view of an embodiment of the prosthetic device of the invention;

Fig. 2 shows a horizontal cross-section of the hollow bodies of the polymeric hollow body component 3 in different packings and sizes;

Fig. 3 illustrates a vertical cross section of an embodiment of the device of the invention where physically/mechanically produced channels are incorporated in solid polymer components 3 and

Fig. 4 is a vertical cross-section of another embodiment of the device of the invention wherein cells are seeded in components 2, 3 and 4.

Fig. 1 depicts a cross-section of the preferred form of a prosthetic device 1 embodying the invention. The device 1 includes at least one superficial layer comprising randomly oriented fibres of the biocompatible and/or at least partially resorbable material 2, a polymeric hollow body component 3, and a base component of a bone substitute material 4.

In principle, any materials can be used for the construction of the device of the invention as long as they are biocompatible. Preferably all materials are biodegradable. In one of the preferred embodiment of the invention the hollow body component 3 and the random fibres component 2 include synthetic polymers or molecules, natural polymers or molecules, biotechnologically derived polymers or molecules, biomacromolecules, or any combination thereof, while the base component 4 is based on a calcium phosphate material.

As can be seen from Fig. 1, the hollow bodies of the polymeric hollow body component 3 are essentially aligned in a direction perpendicular to a top surface of the base component 4, which top surface faces the hollow bodies. The hollow bodies thus form a brush-like structure in a direction perpendicular to the base component 4.

The hollow bodies can be aligned to more than 50 % in a direction perpendicular to the top surface of the base component 4. An alignment of more than 90 % in a direction perpendicular to the base component 4 is preferred, more than 95 % alignment is particularly preferred. The hollow bodies may change alignment direction and self-organize at the uppermost end of the brush like structure. This might occur under pressure after implantation.

The material to be used for the hollow bodies of the hollow body component 3 of the device of the invention is not particularly restricted to specific materials provided, however, the materials are bio-compatible. Preferably, a bio-degradable solid polymer is used which can be of any shape with the proviso that a channel may be provided therein. More preferably, a strang-like solid polymer is used, e.g. made by extrusion. Once the solid polymer has the desired shape, hollow spaces such as channels are formed therein by mechanical, physical and/or chemical methods. Examples for such methods are casting, drilling, etching, etc. which are well known to the person skilled in the art.

For some reason, it may be suitable that the solid polymer is porous. Porosity of the polymer may be provided during manufacturing the polymer.

Preferably, in the device of the invention, the inner channel diameter of the hollow bodies of the polymeric hollow body component 3 is in range of 500 nm to 500 µm, with a preferred range of 5 µm to 150 mm.

The hollow bodies of component 3 of the device 1 of the invention usually have a wall thickness ranging between 1 nm and 500 µm, a wall thickness being between 100 nm and 250 µm is preferred.

The hollow bodies themselves should usually have a height of 50 µm to 10 mm. A height between 100 µm to 2 mm is particularly preferred.

Specifically, the device of the present invention comprises a polymeric hollow body component which is formed by an assembly of oriented tubes. In this case, the space between the assembled tubes is empty or filled with a substance selected from at least one synthetic polymer, natural polymer, biologically engineered polymer, or molecules thereof, biomicromolecules, or any combination thereof.

Fig. 2 depicts in different cross-sections some possible arrangements of the hollow bodies of component 3. With respect to the lateral distribution of the hollow bodies

of component 3, any type of distribution is possible, such as a homogenous or random distribution or a distribution in a specific pattern. Furthermore, the diameter of the hollow bodies and the wall thickness can be homogenous or variable within a hollow body component 3.

Fig. 3 depicts a second preferred form of a prosthetic device 1 embodying the invention. It may be suitable to use a solid or porous block of polymer with manufactured channels as hollow body component 3. There are different methods to create these channels, well-known to persons skilled in the art. Techniques may include erosion, drilling, etching, form casting, etc. Again, channel diameter, and distribution may be homogenous or variable.

In principle, any material can be used for the fibres of the superficial layer 2 which are randomly oriented to form three-dimensional structures of any kind as long as they are biocompatible. In order to enhance the stability of the structure 2, it may be that at least a fraction of material of the fibres is cross-linked. In one preferred embodiment of the invention the fibres 2 include synthetic polymers, natural polymers, biologically engineered polymers, the molecules thereof, biomacromolecules and any combination thereof.

The fibres of the superficial layer 2 themselves are not limited to any structure. They may be straight, twisted,

curled, or of any tertiary structure. It is also possible to use a combination thereof. Additionally, the fibres themselves can be linear, branched or grafted.

The fibres of the superficial layer 2 may be constituted out of single polymer molecules, or out of assemblies of many molecules.

According to the invention, the shape and character of the fibres of the superficial layer 2 can be homogeneous or comprise a combination of various fibres previously mentioned different forms, including chemical, physical composition, and origin. The fibres can form a compact or loose random network, or an at least partially oriented assembly. The fibre-to-fibre distance can be varied within a broad range, i.e. between 1 nm to 1 mm, with a preferred fibre-to-fibre distance of 1 nanometer to 100 micrometers. The distances themselves can be homogeneous or heterogeneous. Examples of heterogeneous distances are gradient-like distributions, or random distributions, or specific pattern alignment, or any combination thereof.

The fibres of the superficial layer 2 of the device of the present invention can be provided as mono-filament or multi-filament fibres of any length. Fiber arrangement in a woven, non-woven twisted, knitted, or any combination thereof is possible. If desired, the lateral cross-section of the fibres 2 can be solid or hollow.

According to the invention, the fiber diameter may be varied in a broad range. Advantageously, a range of 50 nm to 1 mm is proposed. Preferably, the fiber diameter is in range of 1 μm to 250 μm.

It has been shown that one layer of fibres of the superficial layer 2 already brings about good results. However, in some instances, it can be advisable to provide a couple of layers of fibres which is, of course, dependent on the final use of the device of the invention 1. The assembly of multiple layer structures can be a head-head, head-tail, or tail-tail, and any combination thereof. It can also be an intercalated assembly wherein the clear interface border is lost between the different layers and gets continuous.

The superficial layer 2 usually has a thickness of 1 nm to 5 mm. It is preferred that the thickness is in a range of 10 μm to 2 mm. In some instances, however, that layer 2 can be missing and the hollow body component 3 is directly exposed at the surface.

In case of using mineral based materials for the fibre layer 2 and/or the hollow body component 3, a selection may be made from synthetic or natural materials with a glass-like structure, crystalline structure, or any combination thereof.

According to the invention, the fibres of the superficial layer 2 and the hollow bodies of the component 3 may have a flexible structure or a rigid structure depending on the final use of the device 1. In case of adapting to the articulation of a joint or opposing tissue, the fibres 2 should form a flexible structure.

The fiber material is usually homogeneous. Depending on the final use of the device of the invention 1, the fiber material can also be heterogeneous, i.e., selected from various materials or it can comprise an engineered combination of the materials as mentioned above.

In some instances, however, the fibres 2 and/or the hollow bodies of component 3 can be coated or grafted with one or more of the previously mentioned materials.

The device of the present invention 1 comprises, as a further essential structural component, a base component 4. The function of the base component 4 is to anchor the polymeric hollow body component 3 in or onto an osteochondral environment. This osteochondral anchor function helps to keep the device 1 in place when implanted. The base component 4 can be of variable size and shape. Preferably, the shape of the base component 4 is round cylindrical or conical. The diameter of the base component 4 can vary in stepwise manner or in a continuous

transition zone of any size. In practice, the diameter is related to the defect size and ranges between 4 and 20 mm, with a total height being 1 to 30 mm. Preferably, the diameter is in a range of 4 and 20 mm, with a height being between 1 to 10 mm. The top surface of the base component 4 is usually either flat or it mimics the contour of the subchondral plate or the cartilage surface to be replaced.

The material of the base component 4 of the device of the invention 1 can be a material, which is normally used as a bone substitute. Examples of the material are those as listed above in connection with the material of the fibres of the superficial layer 2. If desired, the material for the base component 4 is a mineral material such as synthetic ceramic. The ceramic can be selected out of one or several of the following groups: calcium phosphates, calcium sulphates, calcium carbonates and any mixture thereof.

If the base component 4 of the device 1 is a calcium phosphate, one or more of the following composition groups is preferred: dicalcium phosphate dihydrate ($CaHPO_4x2H_2O$), dicalcium phosphate ($CaHPO_4$), alpha-tricalcium phosphate (alpha-$Ca_3(PO_4)_2$), beta-tricalcium phosphate (beta-$Ca_3(PO_4)_2$), calcium deficient hydroxyl apatite ($Ca_9(PO_4)_5(HPO_4)OH$), hydroxyl apatite ($Ca_{10}(PO_4)_6OH_2$), carbonated apatite ($Ca_{10}(PO_4)_3(CO_3)_3)(OH)_2$), fluoroapatite ($Ca_{10}(PO_4)_6(F,OH)_2$), chloroapatite ($Ca_{10}(PO_4)_6(Cl,OH)_2$),

whitlockite ($(Ca,Mg)_3(PO_4)_2$), tetracalcium phosphate ($Ca_4(PO_4)_2O$), oxyapatite ($Ca_{10}(PO_4)_6O$), beta-calcium pyrophosphate (beta-$Ca_2(P_2O_7)$, alpha-calcium pyrophosphate, gamma-calcium pyrophosphate, octacalcium phosphate ($Ca_8H_2(PO_4)_6x5H_2O$).

It is also possible to have the above mentioned mineral materials doped or mixed with metallic, semi-metallic and/or non-metallic ions, preferably magnesium, silicon, sodium, potassium, strontium and/or lithium.

In another preferred embodiment of the invention, the material of the base component 4 is a composite material comprising at least two different components. Examples of such composite materials are those comprising a mineral, inorganic, organic, biological, and/or biotechnological derived non-crystalline component and a mineral crystalline component. The non-crystalline components are often of polymeric nature.

In a preferred embodiment of the invention, the structure of the materials of the base component 4 is highly porous with interconnecting pores. This would allow any substances and cell in the subchondral environment to diffuse or migrate, respectively, into the base component 4.

In various forms of the invention, at least one of components 2, 3 and 4 has a liquid absorbing capacity by interactions with a solvent. Preferably, the liquid absorbing capacity is in a range of 0.1 to 99.9 %, a range of 20.0 to 95.0 % being particularly preferred.

Usually, the liquid to be absorbed is water and/or body fluid available at the position where the device 1 is implanted. When absorbing water and/or body fluids, the fibres 2 advantageously form a gel or transform to a gel-like state.

Upon uptake of water and/or body fluids the components can swell and, therefore, an internal pressure within the fiber component is built up. That pressure helps stabilizing the structure. Furthermore, externally added components including cells are entrapped under the pressure within the fiber structure as in a natural cartilage.

If desired, the device 1 of the invention may comprise a cell barrier layer between the polymeric hollow body component 3 and the base component 4. This layer acts as a barrier for cells and blood to prevent diffusion from the base component 4 into the polymeric hollow body component 3. It is, however, also possible to provide a barrier layer that is porous and/or has specific pores to allow selective or non-selective cells to pass through.

The interface between random fibre layer 2 and the hollow body component 3, and the hollow body component 3 and the base component 4 respectively, can be formed in various ways. It can be either a chemical, or a physical, or mechanical interaction, or any combination thereof that forms the stabilization zones comprising at least one layer. The stabilization zones can be either formed by material used for device components 2, 3, or 4, or by externally added components, and any combination thereof.

In another preferred embodiment of the device of the invention 1 as illustrated in Fig. 4, at least one externally added component is included in any of the components. Usually said components are dispersed throughout component 2 and/or component 4 and/or component 3. Said components can be cells of different origin. The function is to support the generation of cartilage material and to enhance to improve healing, integration and mechanical properties of the device 1.

The cells are preferably autologous cells, allogenous cells, xenogenous cells, transfected cells and/or genetically engineered cells.

Particularly preferred cells, which can be present throughout the polymeric hollow body component 3 and the fibre layer of 2 are chondrocytes, chondral progenitor

cells, pluripotent stem cells, tutipotent stem cells or combinations thereof. Examples for cells included in the base component 4 are osteoblasts, osteo-progenitor cells, pluripotent stem cells, tutipotent stem cells and combinations thereof. In some instances it can be desired to include blood or any fraction thereof in the base component 4.

Examples for another internally added components are pharmaceutical compounds including growth factors, engineered peptide-sequences, or antibiotics.

An example for another internally added components are gelating compounds including proteins, glycoaminoglycanes, carbohydrates, or polyethyleneoxides. These components can be added as free components, or they can be immobilized within the device of claim 1 by chemical, physical, or entrapment methods to prevent the washing-out.

The polymeric components of the device of the invention may be cross-linked.

The device of the present invention can be directly implanted in a defect, diseased, or deceased cartilaginous area such as articulating joints in humans and animals. Examples of these articulating joints are the cartilage areas in hip, elbow, and knee joints. Usually, implanting

the device into a joint is made by surgical procedures. For example the insertion procedure can be as following:

In a first step, the defect area is cleaned and an osteochondral plug is removed with a chisel. Special equipment allows for exacting bottom and walls with regard to depths and widths. The prosthetic device of the invention is carefully pressed into position in such a manner that the upper edge of the base component 4 is on the same level with the calcified zone dividing the cartilage and the bone. The top surface of the fiber layer 2 should equal the height of the surrounding cartilage. Height differences may be exacted.

The operation can be either carried out in an open or in an arthroscopic manner.

As mentioned above and depicted in Fig. 4, the device of the invention can be seeded with cells and other externally added substances. There are different procedure possible. One of the procedures includes the harvesting of cells prior to the effective operational procedure. After purification and treatment of the harvested cells, they can be seeded either directly into the device 1 for in-vitro cultivation, or subsequent to a short or extended in-vitro expansion and cultivation step, all according to methods established in the art.

An other preferred procedure bypasses extensive in-vitro cultivation and is carried out as an intra-operative procedure. For that, cells are harvested during the operational procedure from the patient, purified and treated according to the methods established in the art. These cells are then seeded into the device 1, and device 1 is immediately implanted into the defect site.

For special applications, it will be also possible to assemble the device of the invention intra-operatively. I.e. the base component 4 is implanted first, and subsequently the hollow body component 3 is immobilized on to the base component 4. The height of the hollow body component 3 is adjusted to the contour of the joint after the immobilization procedure e.g. by shaving or heat treatment. Finally, at least one superficial layer 2 is provided onto the hollow body component 3.

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Claims

1. A triphasic prosthetic device for repairing or replacing cartilage or cartilage like-tissue (1) comprising
   - a polymeric hollow body component (3) with a number of highly oriented hollow bodies;
   - a base component (4) to anchor said polymeric hollow body component (3) in or onto an osteochondral environment and
   - at least one superficial layer comprising randomly oriented fibers (2) provided on said polymeric hollow body component (3)

   wherein said number of highly oriented hollow bodies of the polymeric hollow body component (3) are aligned essentially in parallel to the insertion axis of the prosthetic device.

2. The device according to claim 1, wherein said hollow bodies of the hollow body component (3) are aligned parallel to the axis of insertion to more than 50 %.

3. The device according to claim 2, wherein said hollow bodies are aligned parallel to the axis of insertion to more than 90 %, preferably more than 95 %.

4. The device according to at least one of claims 1 to 3, wherein the inner channel diameter of the hollow bodies of polymeric hollow body component (3) is in a range of 500 nm to 500 μm.

5. The device according to claim 4, wherein said inner channel diameter is in a range of 5 μm to 150 μm.

6. The device according to at least one of claims 1 to 5, wherein the polymeric hollow body component (3) is formed by an assembly of oriented tubes.

7. The device according to claim 6, wherein the space between the assembled tubes is empty or filled with a substance selected from the group consisting of synthetic polymers, natural polymers, biologically engineered polymers, the molecules thereof, biomacromolecules and any combination thereof.

8. The device according to at least one of claims 4 to 7,
wherein the channels have a wall thickness ranging between 1 nm and 500 μm.

9. The device according to claim 8,
wherein the wall thickness is between 100 nm and 250 μm.

10. The device according to at least one of claims 1 to 9,
wherein the hollow body component is a solid block of polymer with channels.

11. The device according to at least one of claims 4 to 10,
wherein the channels are formed by mechanical, physical and/or chemical methods in a solid polymer.

12. The device according to at least one of the claims 1 to 11,
wherein said solid polymer is porous.

13. The device according to at least one of claims 1 to 12,
wherein the lateral distribution of the hollow bodies

of component (3) is homogenous, random or in an specific pattern.

14. The device according to at least one of claims 1 to 13,
wherein said hollow bodies of the hollow body component (3) have a height of 50 μm to 10 mm.

15. The device according to claim 14,
wherein the height is between 100 μm to 2 mm.

16. The device according to at least one of claims 1 to 15,
wherein the fibers of the superficial layer (2) comprise a material selected from the group consisting of synthetic polymers, natural polymers, biologically engineered polymers, the molecules thereof, biomacromolecules and any combination thereof.

17. The device according to at least one of claims 1 to 16,
wherein the base component (4) comprises a bone substitute material.

18. The device according to claim 17,
wherein said bone substitute is a material selected

from the group consisting of synthetic polymers, natural polymers, biologically engineered polymers, the molecules thereof, biomacromolecules and any combination thereof.

19. The device according to claim 17, wherein said bone substitute is a mineral material.

20. The device according to claim 19, wherein said material is a synthetic ceramic.

21. The device according to claim 20, wherein said a synthetic ceramic comprises at least one of calcium phosphate, calcium sulfate and calcium carbonate.

22. The device according to claim 21, wherein said calcium phosphate is selected from the group consisting of dicalcium phosphate dihydrate ($CaHPO_4x2H_2O$), dicalcium phosphate ($CaHPO_4$), alpha-tricalcium phosphate (alpha-$Ca_3(PO_4)_2$), beta-tricalcium phosphate (beta-$Ca_3(PO_4)_2$), calcium deficient hydroxyl apatite ($Ca_9(PO_4)_5(HPO_4)OH$), hydroxyl apatite ($Ca_{10}(PO_4)_6OH_2$), carbonated apatite ($Ca_{10}(PO_4)_3(CO3)_3)(OH)_2$), fluoroapatite ($Ca_{10}(PO_4)_6(F,OH)_2$), chloroapatite ($Ca_{10}(PO_4)_6(Cl,OH)_2$), whitlockite ($(Ca,Mg)_3(PO_4)_2$), tetracalcium phosphate ($Ca_4(PO_4)_2O$), oxyapatite ($Ca_{10}(PO_4)_6O$), beta-calcium

pyrophosphate (beta-$Ca_2(P_2O_7)$, alpha-calcium pyrophosphate, gama-calcium pyrophosphate, octacalcium phosphate ($Ca_8H_2(PO_4)_6x5H_2O$) and mixtures thereof.

23. The device according to claim 20, wherein said synthetic ceramic comprises metallic, semimetallic ions and/or non-metallic ions, preferably magnesium, silicon, sodium, potassium, strontium and/or lithium.

24. The device according to any of the claims 18 to 23, wherein the material is a composite material comprising at least two different components.

25. The device according to any of claims 17 to 24, wherein the bone substitute material is highly porous with interconnecting pores.

26. The device according to any of claims 18 to 25, wherein the shape of the base component (4) is round cylindrical or conical.

27. The device according to claim 26, wherein the diameter of the base component (4) ranges between 4 and 20 mm, with a height being 1 to 30 mm.

28. The device according to claim 27, wherein the diameter of the base component (4) ranges between 4 and 20 mm, with a height being between 1 to 10 mm.

29. The device according to at least of claims 1 to 28, wherein said superficial layer (2) has a thickness of 1 nm to 5 mm.

30. The device according to claim 29, wherein said thickness is in the range of 10 μm to 2 mm.

31. The device according to claim 29 and 30, wherein said superficial layer (2) is missing, or formed by uppermost end of the hollow body component.

32. The device according to at least one of claims 1 to 31, wherein at least one of components (2), (3) and (4) has a liquid absorbing capacity in a range of 0.1 % to 99.9 %.

33. The device according to claim 32, wherein said liquid absorbing capacity is in a range of 20.0 to 95.0 %.

34. The device according to claim 32 or 33, wherein the liquid is an aqueous media and/or a body fluid.

35. The device according to at least one of the preceding claims, wherein the polymeric components are cross-linked.

36. The device according to at least one of preceding claims further comprising at least one externally added component.

37. The device according to claim 36, wherein said components are cells of different origin.

38. The device according to claim 37, wherein said cells are autologous cells, allogenous cells, xenogenous cells, transfected cells and/or genetically engineered cells.

39. The device according to claim 36, 37 or 38, wherein chondrocytes, chondral progenitor cells, pluripotent cells, tutipotent cells or combinations thereof are present throughout the components (2) and/or (3).

40. The device according to claim 36, 37 or 38, wherein osteoplasts, osteo-progenitor cells, pluripotent stem cells, tutipotent stem cells or combinations thereof are present throughout the base component (4).

41. The device according to claim 36, 37 or 38, wherein blood or any fraction thereof is present throughout the base component (4).

42. The device according to claim 36, wherein pharmaceutical compounds are contained.

43. A device according to at least one of the preceding claims, wherein a cell barrier layer is additionally provided between said polymeric hollow body component (3) and said base component (4).

44. A device according to claim 43, wherein the cell barrier layer is a cell selective barrier layer.

45. A use of the device according to at least one of the preceding claims for implantation in articulating joints in humans and animals.

46. The use according to claim 45 for regeneration of articulator cartilagenous tissue.

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Summary

A triphasic prosthetic device for repairing or replacing cartilage or cartilage-like tissue is described. The prosthetic device comprises at a highly oriented hollow body component between a superficial random oriented polymer layer and a base component.

(Fig. 1)

Figure 1

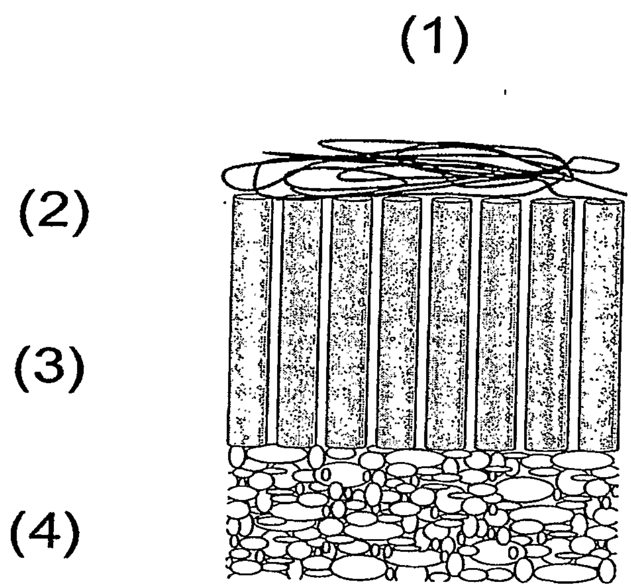

Figure 2

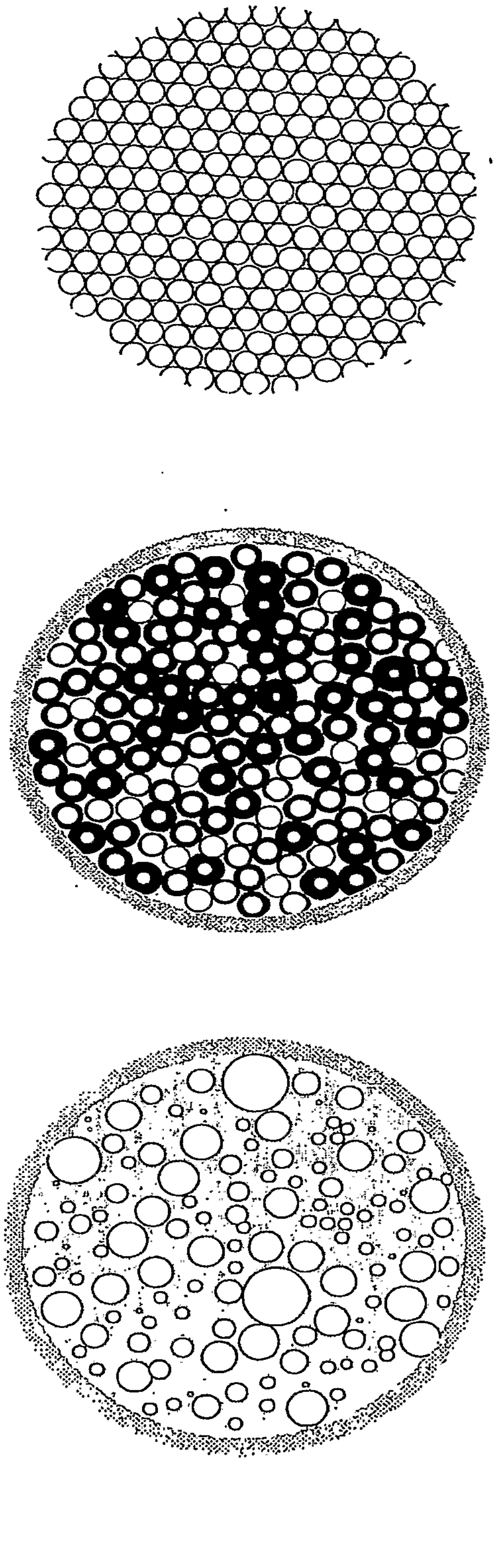

Figure 3

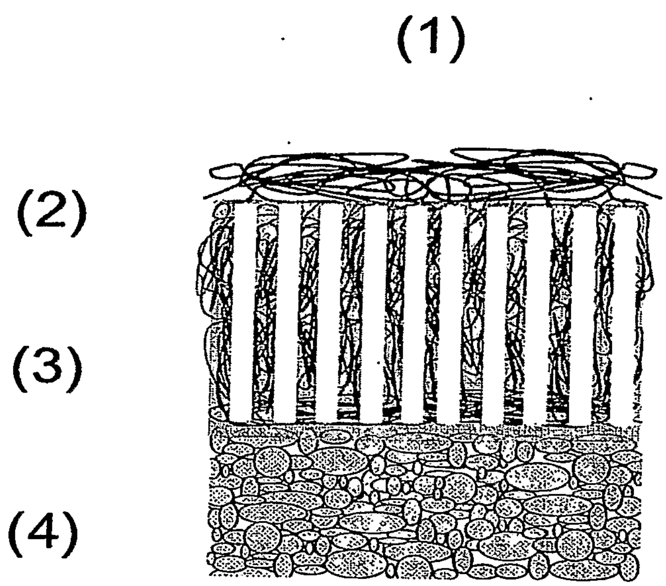

Figure 4